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TUMOR MARKER ASSAY FOR OVARIAN CANCER

Improved Cancer Management

For clinical solutions for the management of gynecologic cancers, Fujirebio Diagnostics, Inc. (FDI) is the exclusive source for the CA 125II radioimmunoassay. CA 125II is an *in vitro* diagnostic device for the quantitative measurement of OC 125 reactive determinants associated with a high-molecular-weight glycoprotein in serum of women with primary epithelial invasive ovarian cancer, excluding those with cancer of low malignant potential.

■ Early Detection of Cancer Recurrence

The CA 125II RIA is indicated for use as an aid in the detection of residual ovarian carcinoma in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures.

■ Enhanced Resolution at the Low End

A second-generation assay, CA 125II uses the M11 mouse monoclonal antibody as the new capture antibody. The addition of the M11 provides the benefit of increased sensitivity and detection at the low end of the curve, resulting in a clearer diagnostic picture and enhanced early disease detection. The M11 antibody is used in a dual monoclonal, heterogeneous format, enabling an easy, single-step procedure.

■ Improved Assay Variability, Clinically Validated

CA 125II has been proven in clinical use to provide a reduction in assay variability by approximately 50% over its predecessor marker.^{1,2} Utilized in a one-step protocol, CA 125II results in minimal assay interference and high inter-assay and intra-assay precision of less than 7% and 5% respectively.²

■ Trusted and Accepted by Physicians Worldwide

Supported by over 2000 peer-reviewed publications, CA 125II is the most widely used tumor marker worldwide for ovarian cancer and is recommended by the National Institute of Health (NIH) to be a useful diagnostic tool for patient follow-up after surgery. CA 125II is manufactured in a proven high-quality process, resulting in a consistent and dependable tumor marker assay.

1. Knapp R., et al: "Clinical perspectives in using CA 125," Contemporary OB/GYN, (1996).
2. Kenemans P., et al: "Heterologous Double-Determinant Immunoradiometric Assay CA 125II," Clinical Chemistry, (1993).



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FDI: THE TRUSTED NAME IN ONCOLOGY DIAGNOSTICS

In the field of oncology diagnostics, Fujirebio Diagnostics, Inc. (FDI) is the name people trust. Formerly Centocor Diagnostics, we pioneered the development of monoclonal antibody technology. Today, FDI is still the unparalleled leader in tumor marker assays worldwide, with innovative products that are unmatched in quality and dependability. FDI's extensive menu of diagnostic products sets the standard for excellence:

- Supported by thousands of peer-reviewed articles
- Endorsed by prestigious academic institutions and medical centers worldwide
- Proven manufacturing process and ISO 9001 certified quality system
- Distributed worldwide by leading healthcare organizations

FDI's Tumor Marker Assays include:

CA 125II™* (Ovarian Cancer) – Used for the quantitative determination of OC 125-defined antigen in serum of women with primary epithelial invasive ovarian cancer, excluding those with cancer of low malignant potential.

CA 19-9™* (Pancreatic Cancer) – Used for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas.

CA 15-3®* (Breast Cancer) – Used for the quantitative determination of DF3-defined antigen in serum or plasma of patients previously treated for stage II or stage III breast cancer.

CYFRA 21-1™*

CA 72-4®*

Other Diagnostic Products:

FITC Anti-Rabies Monoclonal Globulin – Used in the direct fluorescent antibody procedure for the *in vitro* detection of rabies in brains and submaxillary glands.

For more information, call +1.610.240.3800 or visit www.fdi.com

* These products are registered in compliance with the European CE mark.

+ Not for distribution in the United States.

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